

Initials: CSE/DES/cmm Docket No.: 0975.1005-013 Date: October 30, 2001

This is to acknowledge receipt of the following documents each filed under Certificate of Mailing Procedure 37 C.F.R. 1.8:

☒ INFORMATION DISCLOSURE STATEMENT w/copy
☒ Form PTO-1449 pp 1-7 ☒ with references as noted in 1449
☐ Authorization to Charge all Fees
☒ Other Copy of Pending Application and claims for 0975.1005-006

Applicants: Junming Le, et al.
Application No.: 09/927,703 Filed: August 10, 2001
Title: ANTI-TNF ANTIBODIES AND PEPTIDES OF HUMAN TUMOR..

Date received by the PTO:



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C:\SH\DES\emm
10/29/01

PATENT APPLICATION
DOCKET NO.: 0975.1005-013

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and
Scott Siegel

Application No.: 09/927,703 Group Art Unit: 1642

Filed: August 10, 2001 Examiner: Not Assigned

Title: ANTI-TNF ANTIBODIES AND PEPTIDES OF HUMAN TUMOR NECROSIS
FACTOR

CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231	
on <u>10/30/01</u>	<u>Christina McSweeney</u>
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<u>Christina McSweeney</u>	
Typed or printed name of person signing certificate	

OFFICIAL

PG 9/19/03

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
(Filed after payment of issue fee)

09/927,703

-2-

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☐ Copies of the cited references are enclosed.
- ☒ Copies of cited references are enclosed except those entered in prior applications, U.S. Application No. 09/756,398 and Application No. 09/133,119, to which priority under 35 U.S.C. 120 is claimed. The earlier applications contains copies of the cited references.
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) ☐ under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ the enclosed English language abstract.

- ☒ Applicant requests that the following pending applications be considered:

Examiner's
Initials

U.S. Patent Application No. 09/756,398, by Junming Lo, Jan Vilcek, Peter Daddona, John Ghayeb, David M. Knight and Scott Siegel, filed January 8, 2001, Docket No.: 0975.1005-006

09/927,703

-3-

U.S. Patent Application No. 09/756,161, by Junming Le, Jan Vilcek, Peter Daddona, John Ghayeb, David M. Knight and Scott Siegel, filed January 8, 2001, Docket No.: 0975.1005-007

U.S. Patent Application No. 09/756,301, by Junming Le, Jan Vilcek, Peter Daddona, John Ghayeb, David M. Knight and Scott Siegel, filed January 8, 2001, Docket No.: 0975.1005-008

Examiner

Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☒ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. 09/756,398, to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

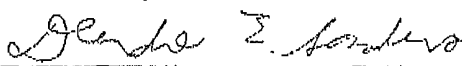
Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By



Deirdre E. Sanders

Registration No.: 42,122

Telephone: (978) 341-0036

Facsimile: (978) 341-0136

Concord, Massachusetts 01742-9133

Dated: *October 29, 2001*

Received from <1 978 341 0136> at 9/29/03 12:11:47 PM [Eastern Daylight Time]

DOC ID NO.: : : OPMA\NHODMA\jman 251118;1

Sheet 1 of 7

PTO-1449 REPRODUCED				ATTORNEY DOCKET NO. 0975.1005-013		APPLICATION NO. 09/927,703	
INFORMATION DISCLOSURE CITATION IN AN APPLICATION October 29, 2001 (Use several sheets if necessary)				APPLICANT Junming Le, et al.			
				FILING DATE August 10, 2001		GROUP 1642	
U.S. PATENT DOCUMENTS							
EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	4,603,106	07/29/86	Cerami et al.	435	7	
	AB	4,822,776	04/18/89	Cerami et al.	514	21	
	AC	5,658,570	08/19/97	Newman et al.	424	184.1	
	AD	5,750,105	5/12/98	Newman et al.	424	133.1	
	AE	5,231,024	7/27/93	Moeller et al.	435	240.27	
	AF	5,888,511	03/30/99	Skurkovich et al.	424	145.1	
	AG	5,958,413	09/28/99	Anagnostopoulos et al.	424	178.1	
	AH	5,993,833	11/30/99	DeLacharriere et al.	424	401	
	AI	5,342,613	08/30/94	Croaven et al.	424	85.1	
	AJ	6,190,691 B1	02/20/01	Mak	424	449	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AL	0212489A2	04 MAR 87	EPO			
	AM	0218868A2	22 APR 87	EPO			
	AN	0288088A2	26 OCT 88	EPO			
	AO	0308378A2	22 MAR 89	EPO			
	AP	0380068A1	01 AUG 90	EPO			
	AQ	0393438A3	24 OCT 90	EPO			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AR	Beutler, B. et al., "Identity of tumour necrosis factor and the macrophage-secreted factor cachectin," <i>Nature</i> , 316:552-554 (1985).					
	AS	Beutler, B. et al., "Passive Immunization Against Cachectin/Tumor Necrosis Factor Protects Mice from Lethal Effect of Endotoxin," <i>Science</i> , 229:869-871 (1985).					
	AT	Morrison, Shorie L., "Transfectomas Provide Novel Chimeric Antibodies," <i>Science</i> , 229:1202-1207 (1985).					
EXAMINER				DATE CONSIDERED			

Sheet 2 of 7

PTG-1449 REPRODUCED				ATTORNEY DOCKET NO. 0975.1005-013		APPLICATION NO. 09/927,703	
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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AL1	0398327A1	22 NOV 90	EPO			
	AM2	0412486A1	13 FEB 91	EPO			
	AN3	0433900A1	26 JUN 91	EPO			
	AO1	0526905A2	10 FEB 93	EPO			
	AP2	WO91/02078	21 FEB 91	PCT			
	AQ2	WO92/07076	30 APR 92	PCT			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AU	Liang, Chi-Ming et al., "Production and Characterization of Monoclonal Antibodies Against Recombinant Human Tumor Necrosis Factor/Cachectin," <i>Biochem. & Biophys. Res. Comm.</i> , 137(2):847-854 (1986).					
	AV	Hirai, Makoto et al., "Production and characterization of monoclonal antibodies to human tumor necrosis factor," <i>J. of Immun. Methods</i> , 96:57-62 (1987).					
	AW	Piquet, Pierre-Francois et al., "Tumor Necrosis Factor/Cachectin is an Effector of Skin and Gut Lesions of the Acute Phase of Graft-vs.-Host Disease," <i>J. Exp. Med.</i> , 166:1280-1289 (1987).					
	AX	Moager, Anthony et al., "Preparation and Characterization of Monoclonal Antibodies Directed Against Antigenic Determinants of Recombinant Human Tumour Necrosis Factor (rTNF)," <i>Hybridoma</i> , 6(3):305-311 (1987).					
	AY	Fendly, Brian M. et al., "Murine Monoclonal Antibodies Defining Neutralizing Epitopes on Tumor Necrosis Factor," <i>Hybridoma</i> , 6(4):359-370 (1987).					
	AZ	Bringman, Timothy S. and Aggarwal, Bharat B., "Monoclonal Antibodies to Human Tumor Necrosis Factors Alpha and Beta: Applications for Affinity Purification, Immunoassays, and as Structural Probes," <i>Hybridoma</i> , 6(5):489-507 (1987).					
	AR2	Tracey, Kevin J. et al., "Anti-cachectin/TNF monoclonal antibodies prevent septic shock during lethal bacteraemia," <i>Nature</i> , 330:662-664 (1987).					
	AS2	Nagai, M. et al., "Antibody to tumor necrosis factor (TNF) reduces endotoxin fever," <i>Experientia</i> , 44:606-607 (1988).					
EXAMINER				DATE CONSIDERED			

Sheet 3 of 7

PTO-1449 REPRODUCED				ATTORNEY DOCKET NO. 0975.1005-013		APPLICATION NO. 09/927,703	
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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AL3	WO92/13095	06 AUG 92	PCT			
	AM3	0260610A2	23 MAR 88	EPO			
	AN3	91/09967	11 JUL 91	PCT			
	AO3	0351789A2	24 JAN 90	EPO			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AT2	Shimamoto, Yoshinori et al., "Monoclonal antibodies against human recombinant tumor necrosis factor: prevention of endotoxic shock," <i>Immunology Letters</i> , 17:311-318 (1988).					
	AU3	Di Giovine, Francesco, S. et al., "Tumour necrosis factor in synovial exudates," <i>Annals of the Rheumatic Diseases</i> , 47:768-772 (1988).					
	AV2	Collins, M.S. et al., "Immunoprophylaxis of Polymicrobial Cellulitis with a Human Monoclonal Antibody Against Lipopolysaccharide Antigen of <i>Pseudomonas aeruginosa</i> ," Abstract E-63, <i>Abstracts of Annual Meeting 1989</i> .					
	AW2	Exley, A.R. et al., "Monoclonal Antibody (Map) to Recombinant Human Tumour Necrosis Factor (rhTNF) in the Prophylaxis and Treatment of Endotoxic Shock in Cynomolgus Monkeys," <i>Medical Research Society</i> , Abstract 184, p. 50 (1989).					
	AX2	Cross, A.S. et al., "Pretreatment with Recombinant Murine Tumor Necrosis Factor α /Cachectin and Murine Interleukin 1 α Protects Mice from Lethal Bacterial Infection," <i>J of Exp Med.</i> , 169:2021-2027 (1989).					
	AY2	Engelmann, Hartmut et al., "A Tumor Necrosis Factor-binding Protein Purified to Homogeneity from Human Urine Protects Cells from Tumor Necrosis Factor Toxicity," <i>J. of Bio. Chem.</i> , 264(20):11974-11980 (1989).					
	AZ2	Kawasaki, Hajime et al., "Analysis of Endotoxin Fever in Rabbits by Using a Monoclonal Antibody to Tumor Necrosis Factor (Cachectin)," <i>Infection and Immunity</i> , 57(10):3131-3135 (1989).					
EXAMINER				DATE CONSIDERED			

PTO. 1419 REPRODUCED				ATTORNEY DOCKET NO. 0975.1005-013		APPLICATION NO. 09/927,703	
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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AP3	0350690A2	17 JAN 90	RPO			
	AQ3	90/00902	08 FEB 90	PCT			
	AL4	WO 92/11383	09 JUL 92	PCT			
	AM4	WO 93/02108	4 FEB 93	PCT			
	AN4	WO 92/16553	19 MAR 92	PCT			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AR3	Fong, Yuman et al., "Antibodies to Cachectin/Tumor Necrosis Factor Reduce Interleukin 1 β and Interleukin 6 Appearance During Lethal Bacteremia," <i>J. Exp. Med.</i> , 170:1627-1633 (1989).					
	AQ3	Von Asmuth, E.J.U. et al., "Tumour Necrosis Factor Alpha (TNF- α) and Interleukin 6 in a Zymosan-Induced Shock Model," <i>Scand. J. Immunol.</i> , 32:313-319 (1990).					
	AT3	Herve, P. et al., "Monoclonal Anti TNF α Antibody for the Treatment of Severe Acute GvHD in Humans," Abstract 3.25, <i>Lymphoma Res.</i> 9:591 (1990).					
	AU3	Silva, Ayona T. et al., "Prophylactic and Therapeutic Effects of a Monoclonal Antibody to Tumor Necrosis Factor- α in Experimental Gram-Negative Shock," <i>J. of Infectious Diseases</i> , 162:421-427 (1990).					
	AV3	Opal, Steven M. et al., "Efficacy of a Monoclonal Antibody Directed Against Tumor Necrosis Factor in Protecting Neutropenic Rats from Lethal Infection with <i>Pseudomonas aeruginosa</i> ," <i>J. of Infectious Diseases</i> , 161:1148-1152 (1990).					
	AW3	Tavernier, Jan et al., "Analysis of the Structure-Function Relationship of Tumour Necrosis Factor. Human/Mouse Chimeric TNF Proteins: General Properties and Epitope Analysis," <i>J. Mol. Biol.</i> , 211:493-501 (1990).					
	AX3	Lucas, R. et al., "Generation and characterization of a neutralizing rat anti-rm TNF- α monoclonal antibody," <i>Immunology</i> , 71:218-223 (1990).					
	AY3	Hinshaw, L.B. et al., "Survival of Primates in LD ₅₀ Septic Shock Following Therapy with Antibody to Tumor Necrosis Factor (TNF α)," <i>Circulatory Shock</i> , 30:279-292 (1990).					
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PTO-1449 REPRODUCED				ATTORNEY DOCKET NO. 0975.1005-013		APPLICATION NO. 09/927,703	
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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AOA	O 867 509 A2	30 SEP 98	EPO			
	AP4	O 861 850 A1	02 SEP 98	EPO			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AZ3	Nophar, Yaron et al., "Soluble forms of tumor necrosis factor receptors (TNF-Rs). The cDNA for the type 1 TNF-R, cloned using amino acid sequence data of its soluble form, encodes both the cell surface and a soluble form of the receptor," <i>The EMBO Journal</i> , 9(10):3269-3278 (1990).					
	484	Engelmann, Marcmut et al., "Two Tumor Necrosis Factor-binding Proteins Purified from Human Urine," <i>J. of Bio. Chem.</i> , 265(3):1531-1536 (1990).					
	AS4	Verhoef, J. and Torensma, R., "Prospects for Monoclonal Antibodies in the Diagnosis and Treatment of Bacterial Infections," <i>Eur. J. Clin. Microbiol. Dis.</i> , 9(4):247-250 (1990).					
	AT4	Loetscher, Hansruedi et al., "Molecular Cloning and Expression of the Human 55 kd Tumor Necrosis Factor Receptor," <i>Cell</i> , 61:351-359 (1990).					
	AU-1	Schall, Thomas J. et al., "Molecular Cloning and Expression of a Receptor for Human Tumor Necrosis Factor," <i>Cell</i> , 61:361-370 (1990).					
	AV4	Akama, Hideto et al., "Mononuclear Cells Enhance Prostaglandin E ₂ Production of Polymorphonuclear Leukocytes via Tumor Necrosis Factor α ," <i>Biochemical and Biophysical Research Comm.</i> , 168(2):857-862 (1990).					
	AW4	Exley, A.R. et al., "Monoclonal antibody to TNF in severe septic shock," <i>The Lancet</i> , 335:1275-1277 (1990).					
	AX4	Möller, Achim et al., "Monoclonal Antibodies to Human Tumor Necrosis Factor α : In Vitro and In Vivo Application," <i>Cytokine</i> , 2(3):162-169 (1990).					
	AY4	Ruddle, Nancy H. et al., "An Antibody to Lymphotoxin and Tumor Necrosis Factor Prevents Transfer of Experimental Allergic Encephalomyelitis," <i>J. Exp. Med.</i> , 172:1193-1200 (1990).					
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	AQ4	0 869 179 A1	07 OCT 98	EPO			
	AL5	0 870 827 A2	14 OCT 98	EPO			
	AMS	0 706 795 A2	17 APR 96	EPO			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AM4	Galloway, Cynthia J. et al., "Monoclonal anti-tumor necrosis factor (TNF) antibodies protect mouse and human cells from TNF cytotoxicity," <i>J. of Immunological Methods</i> , 140:37-43 (1991).					
	ARS	Waldmann, Thomas A., "Monoclonal Antibodies in Diagnosis and Therapy," <i>Science</i> , 252:1657-1662 (1991).					
	ARS	Aderka, Dan et al., "The Possible Role of Tumor Necrosis Factor (TNF) and Its Natural Inhibitors, The Soluble-TNF Receptors, In Autoimmune Diseases," <i>Israel J. Med. Sci.</i> , 28(2):126-130 (1992).					
	AT5	Pennington, James, "TNF: Therapeutic Target in Patients with Sepsis," <i>ASM News</i> , 58(9):479-482 (1992).					
	AUS	Harris, William J. and Emery, Steven, "Therapeutic antibodies - the coming of age," <i>TBTECH</i> , 11:42-44 (1993).					
	AV5	Parrillo, Joseph E., "Pathogenetic Mechanisms of Septic Shock," <i>N.E. Journal of Medicine</i> , 328(20):1471-1477 (1993).					
	ANS	Aggarwal, Bharat B. et al., "Human Tumor Necrosis Factor Production, Purification and Characterization," <i>J. of Biol. Chem.</i> , 260(4):2345-2354 (1985).					
	AK5	Beutler, B. et al., "Purification of Cachectin, A Lipoprotein Lipase-Suppressing Hormone Secreted by Endotoxin-induced RAW 264.7 Cells," <i>J. Exp. Med.</i> , 161:984-995 (1985).					
	AV4	Echtenacher, Bernd et al., "Requirement of Endogenous Tumor Necrosis Factor/Cachectin for Recovery from Experimental Peritonitis," <i>J. of Immunology</i> , 145(11):3762-3766 (1990).					
	ARS	Smith, Craig R., "Human and Chimeric Antibodies to LPS and TNF," 4Abstract, <i>Endotoxemia & Sepsis Conference</i> (1991).					
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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AN5	Q 706 795 A3	17 DEC 97	EPO			
	AO5	WQ98/51344	19 NOV 98	PCT			
	AP5	W000/62790	26 OCT 00	PCT			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AR6	Bodmer, Mark, "Humanized Antibodies for Anti-TNF Therapy," Abstract, Endotoxemia & Sepsis Conference (1991).					
	AS5	Genebank Accession, No. N90300 (1989, November 1).					
	AT6	Genebank Accession, No. M32046 (1990, June 15).					
	AU6	Paulus, H., "Preparation and Biomedical Applications of Bispecific Antibodies", Behring Inst. Mitt, No.78:118-132 (1985).					
	AV6	Parksch, G., et al., "Upregulation of Cytokine Receptors sTNF-R55, sTNF-R75, and sIL-2R in Psoriatic Arthritis Synovial Fluid," J. of Rheumatology, 25:1 105-110 (1998).					
	AW6	Omulecki, A., et al., "Is Pentoxifylline Effective in the Treatment of Psoriasis?", J. of the Am. Academy of Dermatology, 34:4 714-715.					
	AX5	Sagawa, Y., et al., "Is Sustained Production of Tumor Necrosis Factor- α Relevant to the Development of Pustular Psoriasis?", Dermatology, 187:81-83 (1993).					
	AY6	Moase, P.J., et al. "Etanercept in the Treatment of Psoriatic Arthritis and Psoriasis: a Randomised Trial," The Lancet, 356:385-390 (2000).					
	AZ5	Chaudhari, U., et al., "Efficacy and Safety of Infliximab Monotherapy for Plaque-Type Psoriasis: A Randomised Trial," The Lancet, 357:1842-1847 (2001).					
	AR7	Creaven, P.J., et al., "Response to Tumor Necrosis Factor in Two Cases of Psoriasis," J. of Am. Acad. of Dermatology, 24:5(1) 735-737 (1991).					
	AS7	Oh, C.J., et al., "Treatment with Anti-Tumor Necrosis Factor α (TNF- α) Monoclonal Antibody Dramatically Decreases the Clinical Activity of Psoriasis Lesions," J. Am. Acad. Dermatology, 829-830 (2000).					
EXAMINER				DATE CONSIDERED			

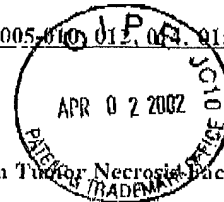
Initials: CSE/DES/JCZ(cmm) Docket No.: 0975.1005-013 Date:

This is to acknowledge receipt of the following documents each filed under Certificate of Mailing Procedure 37 C.F.R. 1.8:

- ☒ SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
 - ☐ w/copy
 - ☐ Form PTO-1449 pp _____ with references as noted in 1449
 - ☐ Authorization to Charge all Fees
 - ☒ Other Copies of co-pending applications for 0975.1005-010, 011, 012, 015, 016, 017 & 018

Applicants: Junming Li, *et al.*
 Application No.: 09/927,703 Filed: August 10, 2001
 Title: Anti-TNF Antibodies and Peptides of Human Tumor Necrosis Factor

Date received by the PTO: ::OPMA\HIDPM\AMMange;296257,1



@PFDesktop\ODMA\MHODMA\ age:289080;1
AOC/DES/ICZ/cinn(rein)
March 29, 2002

PATENT APPLICATION
DOCKET NO.: 0975.1005-013

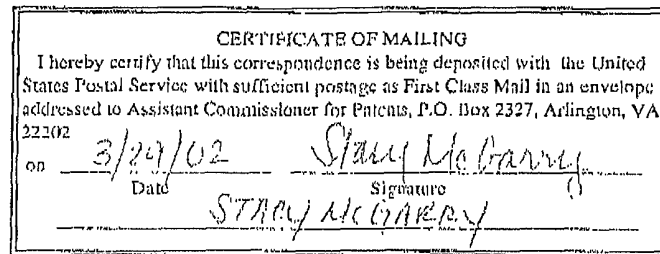
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and
Scott Siegel

Application No.: 09/927,703 Group Art Unit: 1642

Filed: August 10, 2001 Examiner: Not Assigned

Title: ANTI-TNF ANTIBODIES AND PEPTIDES OF HUMAN TUMOR NECROSIS
FACTOR



OFFICIAL
PG 9/29/03

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
P.O. Box 2327
Arlington, VA 22202

Sir:

This Supplemental Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
(Filed after payment of issue fee)

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Statement Under 37 CFR 1.97(c)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☐ Copies of the cited references are enclosed.
- ☒ Copies of cited references are enclosed except those entered in prior application, U.S. Application No. 09/756,398, to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) [] under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ the enclosed English language abstract.

- ☒ Applicant requests that the following pending applications be considered:

Examiner's
bulletin

U.S. Patent Application No. 09/766,535, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 18, 2001, Docket No.: 0975.1005-010

U.S. Patent Application No. 09/897,724, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed July 2, 2001, Docket No.: 0975.1005-012

U.S. Patent Application No. 10/010,229, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed December 7, 2001, Docket No.: 0975.1005-014

U.S. Patent Application No. 10/043,450, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 10, 2002, Docket No.: 0975.1005-015

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U.S. Patent Application No. 10/044,534, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 10, 2002, Docket No.: 0975.1005-016

U.S. Patent Application No. 10/043,432, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 10, 2002, Docket No.: 0975.1005-017

U.S. Patent Application No. 10/043,436, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 10, 2002, Docket No.: 0975.1005-018

Examiner

Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☒ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. 09/756,398, to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By

Deirdre E. Sanders

Deirdre E. Sanders

Registration No.: 42,122

Telephone: (978) 341-0036

Facsimile: (978) 341-0136

Concord, Massachusetts 01742-9133

Dated:

March 27, 2002

DOC ID NO.: 0975.1005-013

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INFO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION March 29, 2002 (Use several sheets if necessary)				ATTORNEY DOCKET NO. 0975.1005-013		APPLICATION NO. 09/927,703	
				APPLICANT Junming Le, et al.			
				FILING DATE August 10, 2001		GROUP 1642	
U.S. PATENT DOCUMENTS							
EXAM- INER INT- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIA TE
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATI ON YES NO
	A05	WO91/09967	11 JUL 91	PCT			
	AL6	0486526B2	07 MAR 01	EPO			
	AM6	WO92/02190	10 JUN 92	PCT			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	A77	Whittle, Nigel, et al., "Construction and Expression of a CDR-Grafted Anti-TNF Antibody," <i>J. Cell Biochem</i> , Supl. 13A:96 (1989).					
	AU7	Gorman, S.D. and Clark, M.R., "Humanisation of monoclonal antibodies for therapy," <i>Sem Immunol</i> , 2:457-466 (1990).					
	AV7	Starnes, H. Fletcher, Jr., et al., "ANTI-IL-6 Monoclonal Antibodies Protect Against Lethal <i>Escherichia Coli</i> Infection and Lethal Tumor Necrosis Factor Challenge in Mice," <i>J Immunol</i> , 145:4185-4191 (1990).					
EXAMINER				DATE CONSIDERED			

Sheet 2 of 3

PTO-1419 REPRODUCED		ATTORNEY DOCKET NO. 0975.1005-013		APPLICATION NO. 09/927,703			
INFORMATION DISCLOSURE CITATION IN AN APPLICATION March 29, 2002 (Use several sheets if necessary)				APPLICANT Junming Le, et al.			
				FILING DATE August 10, 2001		GROUP 1642	
U.S. PATENT DOCUMENTS							
EXAM- JNER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AW7	Duncombe, Andrew S. et al., "Tumor Necrosis Factor Mediates Autocrine Growth Inhibition in a Chronic Leukemia," <i>J Immunol</i> , 143:3828-3834 (1989).					
	AX7	Aderka, Dan et al., "IL-6 Inhibits Lipopolysaccharide-Induced tumor Necrosis Factor Production in Cultured Human Monocytes, U937 Cells, and in Mice," <i>J Immunol</i> , 143:3517-3523 (1989).					
	AY7	Aderka, Dan, "Role of Tumor Necrosis Factor in the Pathogenesis of Intravascular Coagulopathy of Sepsis: Potential New Therapeutic Implications," <i>Isr J Med Sci</i> , 27:52-60 (1991).					
	AZ7	Lassalle, Ph., et al., "Potential Implication of Endothelial Cells in Bronchial Asthma," <i>Int Arch Allergy Appl Immunol</i> , 94:233-238 (1991).					
	AR8	Fong, Yuman and Lowry, Stephen F., "Tumor Necrosis Factor in the Pathophysiology of Infection and Sepsis," <i>Clin Immunol Immunopathol</i> , 55:157-170 (1990).					
	AS8	Eck, Michael J. and Sprang, Stephen R., "The Structure of Tumor Necrosis Factor- α at 2.6 Å Resolution," <i>J Biol Chem</i> , 264:17595-17605 (1989).					
	AT8	Gillies, Stephen D. et al., "High-level expression of chimeric antibodies using adapted cDNA variable region cassettes," <i>J Immunol Methods</i> , 125:191-202 (1989).					
	AU8	Kameyama, Koh-zoh, et al., "Convenient plasmid vectors for construction of chimeric mouse/human antibodies," <i>FEBS Lett</i> , 244:301-306 (1989).					
EXAMINER				DATE CONSIDERED			

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PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 0975.1005-013		APPLICATION NO. 09/927,703			
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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AV8	Hayashi, H. et al., "An Enzyme-linked Immunosorbent Assay for Recombinant Human Tumor Necrosis Factor Using Monoclonal Antibody," <i>Recent Adv. Chemother</i> , 820-821 (1985).					
	AW8	Hirai, Makoto et al., "Production and characterization of monoclonal antibodies to human tumor necrosis factor," <i>J Immunol Methods</i> , 96:57-62 (1987).					
	AX8	Sunahara, N. et al., "Simple enzyme immunoassay methods for recombinant human tumor necrosis factor - and its antibodies using a bacterial cell wall carrier," <i>J Immunol Methods</i> , 109:203-214 (1988).					
EXAMINER				DATE CONSIDERED			